

Paper No. 21

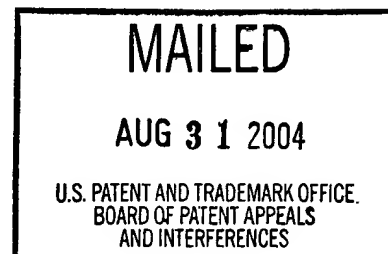
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte RACHEL MEYERS

Appeal No. 2003-1820
Application No. 09/464,039

ON BRIEF



Before WILLIAM F. SMITH, ADAMS, and GRIMES Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 63-67, 77-79 and 87-104, which are all the claims pending in the application.

Claims 63, 77, 79, 87 and 88 are illustrative of the subject matter on appeal and are reproduced below:

87. An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:
- a) the nucleotide sequence set forth in SEQ ID NO:8;
 - b) the nucleotide sequence of the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-2170;
 - c) a nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO:7;
 - d) a nucleotide sequence encoding the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-2170; and

- e) a nucleotide sequence complementary to a nucleotide sequence of a), b), c), or d).

- 63. The nucleic acid molecule of claim 87 further comprising vector nucleic acid sequences.
- 77. A method for detecting the presence of a nucleic acid molecule of claim 87 in a sample, said method comprising the steps of contacting the sample with a nucleic acid probe which selectively hybridizes to the nucleic acid molecule and determining whether the nucleic acid probe binds to the nucleic acid molecule in the sample; wherein said nucleic acid probe is selected from the group consisting of:
 - a) the nucleotide sequence set forth in SEQ ID NO:8;
 - b) the nucleotide sequence of a fragment of the nucleotide sequence set forth in SEQ ID NO:8, wherein said fragment comprises at least 417 contiguous nucleotides of the nucleotide sequence set forth in SEQ ID NO:8;
 - c) a nucleotide sequence having at least 70% sequence identity to the nucleotide sequence set forth in SEQ ID NO:8; and
 - d) a nucleotide sequence complementary to a nucleotide sequence of a), b), or c).
- 79. A kit for use in the method of claim 77, wherein said kit comprises at least one nucleic acid probe of claim 77 and instructions for use in the method of claim 77.
- 88. An isolated nucleic acid molecule having a nucleotide selected from the group consisting of:
 - a) a nucleotide sequence encoding a polypeptide having dehydrogenase activity, wherein said nucleotide sequence has at least 70% sequence identity with the nucleotide sequence set forth in SEQ ID NO:8; and
 - b) a nucleotide sequence complementary to the nucleotide sequence of a).

The references relied upon by the examiner are¹:

Duester, "Families of retinoid dehydrogenases regulating vitamin A function: Production of visual pigment and retinoic acid," Eur. J. Biochem., Vol. 267, pp. 4315-24 (2000)

Rosenberg et al. (Rosenberg), "Gene Therapist, Heal Thyself," Science, Vol. 287, p 1751 (2000)

Wood, "Phenotype Assessment: Are You Missing Something?," Comp. Med., Vol. 50, No. 1, pp. 12-15 (2000)

GROUND OF REJECTION

Claims 63-67, 77-79 and 87-104 stand rejected under 35 U.S.C. § 101 as the claimed invention lacks patentable utility.

Claims 63-67, 77-79 and 87-104 stand rejected under 35 U.S.C. § 112, first paragraph as based on a specification that fails to enable how to make and use the claimed invention.

Claims 88-92 stand rejected under 35 U.S.C. § 112, first paragraph as based on a specification that fails to provide an adequate written description of the claimed invention.

Claim 79 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "instructions for use."

We reverse.

¹ While the examiner states (Answer, page 3), "[n]o prior art is relied upon by the examiner in the rejection of the claims under appeal," the examiner relied upon the references listed herein in the Answer and during prosecution. See e.g., Paper No. 9, pages 3 and 6; and Paper No. 13, pages 3 and 7. Accordingly, it appears that the examiner's statement is in error.

DISCUSSION

Claim Definiteness:

While the examiner recognizes that the limitations of claim 79 relate the claimed kit to the method of claim 77, the examiner asserts (Answer, page 13), “[c]laim 79 is indefinite because it is unclear what are [sic] the ‘instructions for use’ in this context.” In clarifying this assertion, the examiner states (id.), “the scope of [the] instructions for use is not limited to the subject matter of claim 77[,] [f]or example, instructions can include additional products and methods that are not described in the instant specification.”

As we understand the examiner’s statements, it is the examiner’s opinion that even though the kit can be used in the method of claim 77, since the instructions for the use of the kit may make reference to non-disclosed reagents or recite additional method steps, the kit set forth in claim 79 is indefinite. We disagree. As appellant explains (Brief, page 27), claim 79 is drawn to a

“kit for use in the method of claim 77, wherein said kit comprises at least one nucleic acid probe of claim 77 and instructions for use in the method of claim 77.” ... [C]laim 77 specifically recites the essential steps of the claim[ed] method of detection, and one of skill in the art would recognize what is intended by the phrase “instructions for use in the method of claim 77.”

The mere possibility that the instructions included with a kit may include additional method steps or refer to other ingredients other than those set forth in the claimed invention does not necessarily make the description indefinite or extend it beyond appellant’s intent. As set forth in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991):

The statute requires that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed.

In our opinion, a person of ordinary skill in the art would understand what is claimed. Accordingly, we reverse the rejection of claim 79 under 35 U.S.C. § 112, second paragraph.

Utility:

The PTO has the initial burden of challenging a patent applicant’s presumptively correct assertion of utility. In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). If the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility, however, the burden shifts to the applicant to submit evidence sufficient to convince such a person of the invention’s asserted utility. Id.

On this record, appellant discloses (specification, page 1), “[t]he present invention relates to newly identified human alcohol dehydrogenases (ADHs) belonging to the superfamily of mammalian dehydrogenases/reductases.” In this regard, appellant discloses (specification, page 10, emphasis removed), “Figure 15 shows the nucleotide sequence (SEQ ID NO:7) and the deduced amino acid sequence (SEQ ID NO:8) of the novel 21612 ADH.”

According to appellant (Brief, bridging paragraph, pages 3-4), “[t]he function of the novel 21612 polypeptide was determined by comparing the 21612

amino acid sequence set forth in SEQ ID NO:7 to the Pfam database of protein families.” As appellant explains (Brief, page 4),

Pfam alignments do not display homology between pairs of sequences but rather display the fit of a particular query sequence to a particular protein family model. Thus the measure of the strength of a match between the query sequence and the Pfam consensus alignment is the Pfam bit score, which shows the statistical significance of the fit between the query sequence and the Pfam consensus alignment.

According to appellant (Brief, page 5), the Pfam bit score for the 21612 polypeptide is 145, which as appellant explains (id.), “means that the 21612 amino acid sequence is 2^{145} (4.46×10^{43}) times more likely to belong to the short chain dehydrogenase family than to contain the amino acid sequence ... by chance.”²

However, notwithstanding appellant’s arguments and Pfam data, the examiner asserts (id.), “[t]he recited SEQ ID NO(s) are simply computer-generated hypotheses wherein no biological function^[3] has been established.” The examiner, however, offers no evidence to suggest that appellant’s Pfam analysis is not an art-accepted method of determining protein function. Instead, the examiner asserts (id., emphasis removed), “[t]he specification fails to show a single working example that establishes that ... SEQ ID NO: 8 which encodes the amino acid sequence of SEQ ID NO:7 is a member of [the] [a]lcohol dehydrogenase ... family, such as by any substantial sequence homology and/or

² We recognize appellant’s reference (Brief, page 5), to “the Pfam documentation available at <http://pfam.wustl.edu/faq.shtml>...”

³ With reference to Duester, the examiner finds (Answer, page 4), “[i]t is known in the art that [a]lcohol dehydrogenase (ADH) constitutes a complex enzyme system with different forms and extensive multiplicity and the range of ... biochemical reactions which can be catalyzed by ADH is extremely wide.”

functional assay of the protein." In our opinion this assertion, in no way detracts from the weight of appellant's evidence relating to the Pfam bit score for the 21612 polypeptide, placing appellant's polypeptide in the ADH family of proteins, which according to appellant (Brief, page 11), and undisputed by the examiner, is a class of polypeptides having well-established utility.

We also note the examiner's reference (Answer, page 4), to two results (ACC. No. T19954 and ACC. No. AA622988) from an "Office sequence search" to support his assertion that "it is unclear that any ADH-like activity could be attributed to the deduced amino acid sequence of the claimed nucleic acid sequence." However, when confronted with appellant's explanation (see Brief, pages 5-6) of how these two search results support appellant's asserted utility, the examiner switches horses and directs our attention (Answer, pages 8 and 9) to a "US-PTO Pfem [sic]-analysis" which the examiner presents for the first time in the Answer. Not only is the examiner's reliance on this Pfam analysis not properly before this panel⁴, for the following reasons we find it inadequate to support the examiner's assertion.

⁴ See MPEP 1208.01:

A new prior art reference cited for the first time in an examiner's answer generally will constitute a new ground of rejection. If the citation of a new prior art reference is necessary to support a rejection, it must be included in the statement of rejection, which would be considered to introduce a new ground of rejection. Even if the prior art reference is cited to support the rejection in a minor capacity, it should be positively included in the statement of rejection. In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n. 3 (CCPA 1970).

Cf. 37 CFR 1.193(2) (An examiner's answer must not include a new ground of rejection....").

With reference to the Pfam analysis illustrated on page 9 of the Answer, the examiner asserts (Answer, page 8),

[e]ven though the applicant asserts that the amino acid sequences [sic] of SEQ ID NO:7 contain a[n] ADH short chain dehydrogenase-like motif ..., the applicant fails to consider that besides the presence of an ADH shortchain dehydrogenase-like motif the amino acid sequence of SEQ ID N[O]:7 also contain[s] a SCP2 domain ... that is involved in the binding of [s]terols."

From this the examiner reasons (id.), "[c]onsidering the presence of two functionally distinct domains the applicant fails to provide any evidence that the amino acid sequences [sic] of SEQ ID NO:7 has any alcohol dehydrogenase-like activity based upon any alcohol dehydrogenase specific substrate specificity."

The examiner, however, fails to explain why a Pfam bit score of 76.5 (see Pfam illustration, Answer, page 9) for the SCP domain would outweigh the Pfam bit score of 102⁵ (see id.) for the ADH domain. As discussed, supra, appellant explains (Brief, page 5), that the higher the Pfam bit score, the more likely the polypeptide will belong to a particular protein family than to contain the amino acid sequence by chance. Thus, according to the examiner's Pfam analysis (Answer, page 9), appellant's polypeptide sequence is 2^{102} (5.07×10^{30}) times more likely to belong to the short chain dehydrogenase family than to contain the amino acid sequence by chance, while it is $2^{76.5}$ (1.07×10^{23}) times more likely to belong to the SCP2 family than to contain the amino acid sequence by chance. The examiner fails to offer any explanation as to why his Pfam analysis would lead a person of ordinary skill in the art to believe that appellant's polypeptide is

⁵ Or according to appellant's Pfam analysis a bit score 145.

more likely to be a member of the SCP2 family, than a member of the ADH family.

Further, even if appellant's polypeptide contained both an ADH domain and a SCP2 domain, the examiner fails to provide any factual evidence to establish that appellant's polypeptide would not have utility as an ADH. According to appellant's specification (page 2), most dehydrogenase proteins possess at least two domains: the first domain comprising the coenzyme binding site, and the second domain comprising the substrate binding site. This latter domain determines the substrate specificity and contains the amino acids involved in catalysis. Both the examiner's (Answer, page 9), and appellant's (Brief, appendix A), Pfam analysis illustrate that the ADH domain of the claimed polypeptide is at the amino-terminal end of the polypeptide. According to the examiner's Pfam analysis (Answer, page 9), the SCP2 domain is present in the carboxy-terminal end of the polypeptide. This appears to be consistent with appellant's disclosure that most dehydrogenase proteins possess at least two domains. Accordingly, we are not persuaded by the examiner's arguments with regard to the Pfam analysis.

We are also not persuaded by the examiner's statement (Answer, page 8), that appellant's "arguments would be persuasive if they have demonstrated the catalytic oxidation of a single SDR [short chain dehydrogenase] substrate using the claimed amino acid sequences." The examiner, however, fails to identify any rule of law, and we know of none, that requires appellant's specification to contain a working example. Cf. In re Strahilevitz, 668 F.2d 1229,

1232, 212 USPQ 561, 563 (CCPA 1982) (“examples are not required to satisfy section 112, first paragraph.”).

In addition, we are not persuaded by the examiner’s suggestion (id., emphasis added) that since appellant’s polypeptide is 418 residues long and SDRs “typically have subunits containing approximately 250^[6] residues,” appellant’s polypeptide is not an ADH. The examiner, however, fails to establish a nexus between a subunit (e.g. a domain) of a polypeptide and the full-length polypeptide. Stated differently, the examiner fails to provide any evidence demonstrating that proteins in the SDR family are typically only about 250 residues in length.

For the foregoing reasons, it is our opinion that the examiner failed to provide the evidence necessary to meet his burden of challenging applicant’s presumptively correct assertion of utility. Accordingly, we reverse the rejection of claims 63-67, 77-79 and 87-104 under 35 U.S.C. § 101.

Enablement:

To the extent that the examiner’s assertions are simply a corollary to his finding of a lack of utility (See e.g., Answer, page 10) our conclusion with regard to the rejection under 35 U.S.C. § 101, also applies to the rejection under 35 U.S.C. § 112. We note, however, that the examiner has made additional arguments with regard to the enablement rejection. Accordingly, we focus our attention on these additional arguments. We note, however, “[w]hen rejecting a claim under the enablement requirement of section 112, the PTO bears an initial

burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification.” In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Carrying that burden requires evidence or sound scientific reasoning showing that practicing the full scope of the claims would have required undue experimentation. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (“[E]nablement requires that the specification teach those in the art to make and use the invention without ‘undue experimentation.’ . . . That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is ‘undue.’”).

On this record, the examiner finds (Answer, page 5, emphasis added), “the claimed invention is drawn to the polypeptide encoded by the nucleic acid sequences which hybridize to nucleic acid sequence of SEQ ID N[O]:8 or have 70-90% sequence identity to SEQ ID NO:8 (see claims 88-90)[.]” In this regard, the examiner finds (id.), “[t]he variants as claimed encompass 10-30% nucleotide sequence variation over the entire length of SEQ ID NO:8.” Thus, the examiner concludes (id.), “[t]he claimed invention is not enabled in view of [sic] lack of teachings in the specification as filed regarding what additional sequences may be added, deleted or substituted to those specifically disclosed, such that asserted [sic] utility discussed in the section 101 rejection above would be recognized as specific and/or substantial.”

⁶ The examiner relies on page 4316 of Duester to support this assertion.

At the outset we recognize the examiner's focus on claims 88-90. Claims 77-79, and 98-100, however, also contain similar "% identity" language, and claim 91 is drawn to a nucleic acid molecule that hybridizes to the nucleotide sequence set forth in SEQ ID NO:8. The examiner, however, makes no reference to claims 77-79, 91 or 98-100.⁷ Accordingly, it appears that the examiner has treated the claims in this application in an inconsistent manner. Further, each of claims 88-90 requires that the nucleotide sequence encode a polypeptide having dehydrogenase activity. Thus, despite some degree of variation in the nucleotide sequence the claimed nucleic acid molecule must encode a polypeptide having dehydrogenase activity.

We are also not persuaded by the examiner's statement (Answer, page 5), "[i]t is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if...." The examiner's reference to "general knowledge," does not fulfill his obligation to cite references to support his conclusions. Cf. In re Lee, 277 F.3d 1338, 1344, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002). In our opinion, the examiner failed to meet his burden of providing the evidence necessary to establish a lack of an enabling description.

In addition, we find it unclear, as to why the examiner believes that to enable the claimed invention the specification must disclose the role, if any, that the claimed polypeptides play in a disease. Answer, page 6. As set forth above,

⁷ Cf. the examiner's rejection of claims 88-92 under the written description provision of 35 U.S.C. 112, first paragraph, infra, where the examiner focuses our attention on the "% sequence identity."

appellants have asserted that alcohol dehydrogenases, as a class, have a well-established utility. Brief, page 11. The examiner has not disputed this assertion.

Nevertheless, it may be that the examiner linked this argument to his belief that since claims 65-67 and 95-97 are drawn, inter alia, to a host cell containing nucleic acid these claims read on gene therapy, and/or the production of transgenic animals. See e.g., Answer, page 6. However, no claim on appeal is directed to the treatment or diagnosis of a disease, nor is any claim on appeal directed to a gene therapy method, or method of producing a transgenic animal. See Brief, page 20, wherein appellant asserts "the claims are not directed to methods of gene therapy or to methods of producing a transgenic animal having a particular phenotype but instead are directed to host cells containing specified nucleic acid molecules."

While it is true that appellant's specification discloses the use of ADH polynucleotides for use in "gene therapy" (see e.g., specification, page 79 and 88), and in the production of transgenic animals (see e.g., specification, page 68), we remind the examiner that "[t]he enablement requirement is met if the description enables any mode of making and using the invention." Johns Hopkins Univ. v. CellPro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998) (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)).

According to appellant's specification (page 88), host cells are useful for: "producing ADH proteins or polypeptides"; "conducting cell-based assays involving the ADH or ADH fragments"; "identifying ADH mutants"; and etc. The examiner has not explained why the specification does not enable these uses of the host cells. Absent evidence to the contrary from the examiner, we have no reason to doubt appellant's presumptively enabled specification. In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Since the specification describes one method of making and using the invention of claims 65-67 and 95-97, it enables those claims, whether or not the claimed method is also enabled for use in gene therapy, or in the production of transgenic animals.

For the foregoing reasons we reverse the rejection of claims 63-67, 77-79 and 87-104 under the enablement provision of 35 U.S.C. § 112, first paragraph.

Written Description:

The examiner has the initial burden of establishing that appellant's specification does not satisfy the written description provision of 35 U.S.C. 112, first paragraph. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).

According to the examiner (Answer, page 6), claims 88-92 "are drawn to a nucleotide sequence encoding a polypeptide having dehydrogenase activity, wherein the nucleotide has at least 70-90% sequence identity with [the]

nucleotide sequence of SEQ ID NO:8." In this regard, the examiner finds (id.), "[t]he specification as [filed] fails to disclose any and all variant [sic] of human alcohol dehydrogenase comprising the nucleic acid sequence of SEQ [ID NO:] 8, which encodes the amino acid sequences [sic] of SEQ ID NO:7."

While the examiner recognizes (Answer, page 12, emphasis removed), "possession may be shown ... by describing the invention with sufficient relevant identifying characteristics ... such that a person skilled in the art would recognize that the inventor had possession of the claimed invention," the examiner asserts (Answer, bridging sentence, pages 12-13), "the 21612-polynucleotides has [sic] been defined only by a statement of function of short chain alcohol dehydrogenase activity, which conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics." According to the examiner (Answer, page 7), appellant discloses SEQ ID NO:8, and "proposes to discover other members of the genus using hybridization procedure [sic]."

Initially, we agree with appellant (Brief, page 21),

"the [e]xaminer has presented no evidence to demonstrate that one of skill [in] the art would doubt the credibility of [a]pplicant's assertion that the 21612 polypeptide functions as a dehydrogenase. Accordingly, the premise on which the rejection is based, i.e. that the 21612 polypeptide does not have dehydrogenase activity, is not supported by the evidence of record." Brief, page 21.

In addition, appellant argues (Brief, page 22), claims 88-92 “recite the identifying structural characteristics that define each genus of nucleotide sequences”

Specifically, appellant points out (Brief, bridging paragraph, pages 22-23),

[c]laims 88-90 recite nucleotide sequences having at least 70%, 80%, or 90% sequence identity with the nucleotide sequence set forth in SEQ ID NO:8, claim 91 recites nucleotide sequences that hybridize to the nucleotide sequence set forth in SEQ ID NO:8 under specified conditions, and claim 92 recites nucleotide sequences encoding a fragment of the amino acid sequence set forth in SEQ ID NO:7 or the amino acids [sic] sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-2170....

In addition, appellant points out (Brief, page 23), “claims 88-92 recite that the variants and fragments have dehydrogenase activity.”

On this record, we have the amino acid sequence of the protein, SEQ ID NO:7. In In re Wallach, No. 03-1327, 2004 WL 1780989, at *3 (Fed. Cir., Aug. 11, 2004), our appellate reviewing court found

the state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it, and that one of ordinary skill in the art ... [in 1995] may have therefore been in possession of the entire genus of DNA sequences that can encode the ... protein sequence, even if individual species within that genus might not have been described or rendered obvious.

In this regard, we note that the instant application was filed in 1999. Thus, it appears that appellant was in possession of all variants within the genus of DNA sequences that can encode the protein sequence set forth in SEQ ID NO:7.

Further, as appellant points out (Brief, page 15), the claims are limited to nucleotide sequences meeting both the structural requirements of these claims and the claimed functional requirement – having dehydrogenase activity. Both appellant's and the examiner's Pfam analysis (see Answer, page 9) demonstrate that a person of ordinary skill in the art at the time the invention was made would recognize the relevant structural characteristics of appellants' claimed invention that are necessary to place a polypeptide encoded by a nucleic acid variant of SEQ ID NO:8 in the dehydrogenase family of proteins. The examiner provides no evidence on this record that the Pfam analysis cannot be used to assign a function to a protein.

Further, as discussed supra, while the examiner focuses our attention on claims 88-92, we note that claims 77-79, and 98-100 also contain similar "% identity" language. The examiner, however, makes no reference to claims 77-79 or 98-100. Accordingly, it appears that the examiner has treated the claims in this application in an inconsistent manner.

For the foregoing reasons, it is our opinion that the examiner failed to meet his burden of providing the evidence necessary to maintain the rejection of claims 88-92 under the written description provision of 35 U.S.C. § 112, first paragraph. Accordingly, we reverse the written description rejection.

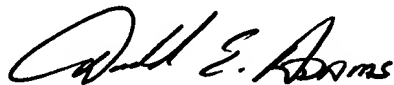
SUMMARY

For the foregoing reasons, it is our opinion that the examiner failed to meet his evidentiary burden in each of the rejections of record. Accordingly, all rejections of record are reversed.

REVERSED


William F. Smith

Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge

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